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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/486,070	06/07/1995	JANNIS G. STAVRIANOPOULOS	ENZ-7(P)(C3)	6279
28171	7590	09/29/2005		
ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			EXAMINER MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 09/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/486,070

Applicant(s)

STAVRIANOPOULOS ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) (See attached list.) is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) (See attached list.) is/are allowed.
- 6) ☒ Claim(s) (See attached list.) is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

(db)

**Claim listings from the attached 326 form:**

Pending claims 4): 3144-3147, 3150-3155, 3157-3169, 3172-3175, 3179-3183, 3185-3201, 3204-3209, 3211-3224, 3227-3232, 3234-3238, 3240-3248, 3252-3256, 3258-3268, 3271-3277, 3279-3283, and 3287-3407

Allowed claims 5): 3144-3146, 3150-3155, 3157-3169, 3172-3174, 3179-3183, 3185-3197, 3222-3224, 3227-3232, 3234-3238, 3240-3247, 3252-3256, 3259-3268, 3271-3274, 3279-3283, 3287-3291, 3294-3299, 3310-3325, 3328-3361, and 3380-3407

Rejected claims 6): 3147, 3175, 3198-3201, 3204-3209, 3211-3221, 3248, 3258, 3275-3277, 3292, 3293, 3300-3309, 3326, 3327, and 3362-3379

**DETAILED ACTION**

Applicants' arguments, filed 5/25/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

**NEW MATTER**

Claims 3147, 3175, 3198-3201, 3204-3209, 3211-3221, 3248, 3302-3309, 3326, 3327, and 3362-3379 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The NEW MATTER rejection based on NEW MATTER being amended into instant claim 3147 etc. directed to "beads" is maintained and reiterated from the previous office action, mailed 11/26/04, due to these limitations still being present in certain claims and not supported by written disclosure as filed. Applicants have newly added the limitation "a bead" (e.g., claim 3147, line 4) which also is NEW MATTER due to not being found as filed regarding written description. This "a bead" rejection basis is necessitated by amendment. The NEW MATTER directed to "a bead" or "beads" was not addressed as to written description specifically as filed by applicants in their response, filed 5/25/05. In an appendix applicants point to pages 13-14; page 14, lines 19-20; page 16, lines 10-11; Examples 1-3 and 5-7; and claims 17 and 21 as originally filed; of the specification for written support for claim 3147, for example, but neither a bead or beads is found therein. These NEW MATTER limitations are present in claims 3147, 3175, 3201, and 3248.

The NEW MATTER rejection directed to a lack of written description as filed for a generic "array" comprising "various" nucleic acids is maintained and reiterated from the

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previous office action, mailed 11/26/04. In contrast, the arrays with depressions or wells for depositing of various denatured analytes has written basis in Example 1 as filed.

Thus, the "various" nucleic acids limitation is connected as filed to depressions or wells for depositing of various analytes. Applicants argue that plural sequences in the specification supports generic arrays with various nucleic acids thereon. This has been responded to previously and the response is repeated that plural sequences may either be the same or different and that the phrase "plural sequences" lacks written support for different or various as a particular type of plural sequences. Applicants again also note a Declaration of Dr. Alexander A. Waldrop, III, which has been responded to previously as being non-persuasive. Applicants further argue that the novelty of the invention resides in fixing nucleic acids in hybridizable form to the surface of a substrate regardless of its shape. In response, this NEW MATTER rejection basis is not directed to claims which cite plural sequences or surface(s) of a substrate regardless of shape. This rejection is directed to claims which specifically cite "various" nucleic acids which indicates some type of variation of nucleic acid type which as filed is only described wherein depressions or wells are practiced apparently to separate one variant from another therebetween the depressions or wells. Such a consideration is not required when plural nucleic acid molecules or sequences are utilized without any distinction as to type or variousness. When applicants, as filed, describe various nucleic acids they also reasonably indicate depressions or wells for separation of the various nucleic acid types. Applicants then argue that In re Peters is analogous in that tapered and non-tapered tips has written support and note that the CCPA indicated that the tip

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configuration was non-critical. In response, this fact pattern is distinguished over that of the instant claims because the nucleic acid hybridization practice includes an enabling usage of detection of analyte targets specific to the nucleic acid probe utilized and therefore separation in depressions or wells of variants of nucleic acid for detection purposes is critical when variants are utilized in order to maintain whatever desired target specificity is present regarding various probe nucleic acids. Various training materials are then set forth by applicants but again supporting only non-critical elements as having written basis where no relationship is required in contrast to the instant invention wherein hybridization probe specificity distinguishes various or different nucleic acid targets which would be obscured and useless if separations of some type, such as wells or depressions, were not envisioned by applicants as filed to separate various analyte detection elements. No other separation practice was disclosed as filed between various nucleic acids. Applicants argue further regarding "non-porous solid support" support. This section again ignores the hybridization probe specificity regarding target detection which is a critical feature thereof and only described as filed wherein various nucleic acids are immobilized in wells or depressions in order to obtain a detection result separated between various or different nucleic acid probes. This argument also seems to be directed to instant broad claims which do not require various nucleic acids which argument is moot regarding this basis for rejection because it is directed only to claims containing the "various...nucleic acids" limitation. Applicants go on to argue that *Bilstad v. Wakalopoulos* explained two commonly recognized exceptions regarding "plurality". The Federal Circuit was cited as determining that disclosure of a

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specie may be sufficient written description support for a later claimed genus including that specie. In response, this argument is again apparently directed to the broad instant claims which lack a "various...nucleic acids" limitation and therefore is moot regarding this rejection. Additionally, there is no indication as filed that the specie of "various...nucleic acids" with its well known probe specificity character may or should be generically applied to surfaces other than those with depressions or wells, especially since the depressions or well as discussed above reasonably effect a separation of probes for detection facilitation of each probes specific target detection capability. Again applicants argue that Dr. Waldrop's Declaration should be given relevant weight and is not an opinion Declaration. In response, this Declaration was discussed in the record previously as being a Declaration which failed to provide written basis as filed for the generic array containing "various...nucleic acids". Also, contrary to applicants' argument, Item 14 in said Declaration clearly states that it is an "opinion" Declaration. In particular Item 15 of said Declaration cites an example providing glass plates with an array of depressions or wells with "various denatured analytes" and then confusingly, and in direct conflict, declares that the reference is not limited to depressions or wells. Additionally, the Declaration fails to indicate what disclosure as filed supports the various nucleic acids with their hybridization specificity as to any detection practice corresponding thereto generic array surfaces which is a reasonable summary of the remainder of said Declaration. It is reiterated that such a Declaration is not written basis as filed. Applicants further argued missing several points in said Declaration but confusingly fail to indicate what those points are. Thus, such points cannot be

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responded to. Applicants then argue regarding *In re Alton*. In response, the fact pattern in *In re Alton* is different from the instant disclosure as filed and therefore non-persuasive. In the consideration of *In re Alton*, the persuasive Declaration indicated an independence of different IFN amino acid substitutions/alterations wherein an amino terminus alteration did not functionally relate to another amino acid substitution well within the polypeptide. Thus, there was an independence of amino acid substitution and/or deletion which supported the analysis of the therein discussed Declaration as being persuasive. The Declaration of Dr. Waldrop, III, in contrast, sets forth the argument that the disclosure as filed describes a number of surfaces or substrates but lacks any indication of the independence on which the *In re Alton* decision relies thus making this argument non-persuasive. Also, the locating of various nucleic acids is functionally important for specific target or analyte detection in the instant disclosure example which is not required or even significant in the *In re Alton* case. It is also noted that there is no indication of plural sequences being located with any particularity on any generic array in the instant disclosure as filed nor even that there is any separation whatsoever between any of the plural sequences so as to functionally result in specific and separate detection which is the only hybridization probe use that may relate to plural sequences if they were, in particular, inclusive of variants or different types. Thus, there is no generic array that has written support as filed on which various nucleic acids are attached or immobilized etc. This rejection applies to instant claims 3198-3201, 3204-3209, 3211-3221, 3302-3309, 3326, 3327, and 3362-3379; either as reiterated or necessitated by amendment for newly added claims.



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### **VAGUENESS AND INDEFINITENESS**

Claims 3258, 3275-3277, 3292, and 3293 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection based on "indirectly" fixed or immobilized is reiterated and maintained from the previous office action, mailed 11/26/04. Applicants only argument regarding this rejection basis is that claim amending has removed the unclear direct or indirect wording. Review of the instant claims, however, reveal that several claims still contain the limitation "indirectly" as related to fixed or immobilized limitations as listed above. Certain newly added claims contain this limitation as necessitated by amendment, for example, as claim 3292 which contains this unclarity due to depending from claims 3275 or 3276.

### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3300-3302, 3306, 3308, 3362, 3366-3370, 3373, and 3376-3378 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Stuart et al. (P/N 4,732,847).

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This rejection is reiterated from the previous office action, mailed 11/26/04, as necessitated by amendment regarding newly added claims as listed above directed to single stranded polynucleotides fixed or immobilized in hybridizable form to a non-porous solid support, such as a glass slide as set forth previously regarding this rejection. The above listed claims are disclosed in the reference via previously set forth disclosure in Stuart et al. whereby supports were listed as well as detection via various labels that are colored etc. and quantifiable via said color detection. Applicants argue that the amendments directed to supports comprising amine(s), hydroxyl(s), or epoxide(s) are distinguished over this prior art reference. In response, such instant claims as being so limited are not rejected hereinunder. The above listed claims, however, are broader in scope and do not require such specifically functionalized supports. No other argument was set forth by applicants that pertains to this rejection.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicant, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 41.37. Upon the timely filing of a second submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 41.20(b) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 20, 2005

*Ardin H. Marschel 9/27/05*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**